# EXHIBIT J

U.S. Department of Health & Human Services

# News Release

FOR IMMEDIATE RELEASE
Tuesday, December 11, 2007

Contact: HHS Press Office
(202) 690-6343

## Statement by Secretary Mike Leavitt, Secretary of Health and Human Services, On Signing Memoranda of Agreement between the United States and The People's Republic of China to Improve the Safety of Food, Feed, Drugs and Medical Devices

Six months ago, my colleagues in China and I began a conversation about how we could improve the safety of the food and health products upon which our two countries have come to rely. Four sets of formal talks followed, and today in Beijing we signed two important Memoranda of Agreement, one concerning food and feed, and the other drugs and medical devices. These strong, action-oriented documents require specific steps and set clear deadlines. Taken together, these agreements will enhance the safety of scores of household items the American people consume on a daily basis.

The agreements satisfy our firm principle that any country that desires to produce goods for American consumers must do so in accordance with American standards of quality and safety. To help accomplish this, the two documents apply a three-pronged strategy of registration, certification and verification.

First, all Chinese producers of items covered under the agreement must register with Chinese authorities, who will share that data with HHS. Second, Chinese regulators will certify that food and feed covered by the agreement meet our standards. They will pursue a method to certify medical products as well. Third, to verify compliance, the Chinese are adopting quality-assurance methods every step of the way. For example, Chinese authorities will develop a comprehensive electronic tracking system to follow products from production to exportation. This will help ensure that growers and manufacturers are building quality into their processes and that we can take action if they do not.

Another critical aspect of these agreements is information sharing. Chinese authorities have pledged to provide timely notification to U.S. regulators under a wide range of circumstances, including the failure of a facility to meet inspection requirements and the suspension or revocation of a manufacturer's certification status. Inspectors from HHS' Food and Drug Administration will also gain broader access to Chinese production facilities and on an expedited basis.

President Bush has made ensuring the safety of imported products a top priority. This summer, he appointed me to chair a Cabinet-level Working Group on Import safety, made up of twelve Federal Departments and agencies. We crisscrossed the country, and talked with those on the front lines to gain a better understanding of how the import process works, and how the private sector and we in government can improve it.

Over the course of that work, I found the United States has a good system to assure the safety of imports today, but it is not adequate for the future. This year alone, we will import $2 trillion worth of goods into this country from 825,000 importers, through more than 300 points of entry. Also, analysts expect that volume of trade to continue to grow sharply. To keep up with the pace of global commerce, we need a fundamental shift, from trying to catch unsafe products as they come in, to building quality and safety into products before they reach our borders.

The Action Plan on Import Safety I presented to President Bush on November 6 articulates this new approach, and the agreements with the Chinese government we signed today embody it. These agreements are an important contribution to the U.S. government's efforts to enhance the safety of imported goods, and I look forward to seeing concrete, measurable results as we implement them.

Drugs and Medical Devices Agreement>>
Food and Feed Agreement>>

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Note: All HHS press releases, fact sheets and other press materials are available at *http://www.hhs.gov/news*.

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## U.S. Department of Health & Human Services

# New Agreement Will Enhance the Safety of Food and Feed Imported From the People's Republic of China

FOR IMMEDIATE RELEASE
Tuesday, Dec. 11, 2007

Contact: HHS Press Office
(202) 690-6343

On December 11, 2007, the U.S. Department of Health and Human Services (HHS) and the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) of the People's Republic of China signed a Memorandum of Agreement (MOA) to enhance the safety of food and feed imported into the United States from China. HHS Secretary Mike Leavitt and the Honorable Li Changjiang, Minister of AQSIQ, signed the Agreement in Beijing in advance of the third session under the United States-China Strategic Economic Dialogue.

Specifically, the two countries are establishing a bilateral mechanism to provide greater information to ensure products imported into the United States from China meet standards for quality and safety. Implementation of the agreement will begin with a determined list of products, such as preserved foods (e.g. canned mushrooms, olives, various vegetables), pet food/pet treats of plant origin or animal origin, raw materials used in making manufactured foods (e.g. wheat gluten and rice protein used in canned and dry pet food for dogs and cats), and farm-raised fish (e.g. shrimp and catfish). The two sides can add additional products by mutual agreement.

**Key Terms of Agreement**

***New Registration and Certification Requirements.*** To enhance the safety of products sold in the U.S., Chinese authorities will implement two programs, both subject to an audit by the Food and Drug Administration (FDA) within HHS. The first will require exporters to the United States to register with AQSIQ and agree to annual inspections to ensure their goods meet U.S. standards. AQSIQ will notify HHS/FDA of those that fail inspection, and why. HHS/FDA will maintain an online list of registered companies. AQSIQ will also notify HHS/FDA of all companies AQSIQ suspended or that have lost their registered status. To better contain and resolve safety problems, AQSIQ will implement a system to trace products from the source of production or manufacture to the point of exportation.

Second, new certification requirements will help ensure products exported from China to the United States meet our standards. Once AQSIQ's Inspection Bureau confirms a shipment meets HHS/FDA requirements, it will issue a certificate that carries a unique identifying number, which AQSIQ must also file with HHS/FDA. To avoid counterfeit certificates, technical experts from both countries will work together to implement a secure electronic system. AQSIQ will also develop a testing program that provides, as determined by HHS/FDA, a high level of statistical confidence in the quality of products exported to the United States.

HHS/FDA will explore mechanisms to notify AQSIQ when shipments of products exported to the United States are not certified, or come from a company not registered with AQSIQ.

***Greater Information-Sharing.*** Each party commits to notify the other within 48 hours of the emergence of significant risks to public health related to product safety, recalls, and other situations. In the past, there was no system of notification. HHS/FDA can request a timely investigation regarding any covered product if there is reason to believe it could pose a health or safety risk.

***Increased Access to Production Facilities.*** AQSIQ will assist and facilitate the inspection of manufacturing, cultivation, or processing sites in China by HHS/FDA. The two countries will develop joint training programs and activities, including in laboratory and risk-assessment methodologies and compliance and enforcement programs.

***Implementation and Establishing Key Benchmarks.*** HHS/FDA and AQSIQ will create a Working Group to meet within 60 days to develop a plan that further details specific activities each will undertake to implement the agreement, and to establish performance measures to evaluate progress. To do so, HHS/FDA could rely on benchmarks such as the rate at which HHS/FDA refuses entry of covered products into the United States; the percentage of items exported to the United States that are uncertified or exported by companies not registered with Chinese authorities; and the volume, frequency and public-health significance of products recalled, including counterfeit goods, as compared to the previous year. The Working Group will meet annually.

**Background**

In July, President Bush appointed Secretary Leavitt to chair a Cabinet-level Working Group on Import Safety, made up of twelve Federal Departments and agencies. Members of the Working Group visited ports, border crossings, supermarkets, retailers, meat and seafood processing facilities, and wholesalers across the United States to gain a better understanding of the vast import process. Secretary Leavitt also met with his counterparts from G-7 nations, Mexico, and the European Commission to discuss common import-safety challenges. On Nov. 6, 2007, the Working Group presented an Action Plan to the President made up of short- and long-term recommendations to bolster the safety of the increasing volume of imports that are entering the United States.

The MOA complements the vision and goals outlined in the Action Plan, and will serve to build on efforts already underway by the U.S. Government to enhance the safety of imported products.

During the second session of the United States-China Strategic Economic Dialogue in May 2007, HHS/FDA and SFDA launched negotiations on a binding MOA on the safety of food and feed exported from China to the United States. The negotiations resulted from a growing concern over ensuring the safety, quality, and effectiveness of many Chinese products exported to the United States.

Over the course of four sets of talks from July to November 2007, senior officials from HHS/FDA engaged in negotiations with senior officials from a number of agencies in the Chinese government. The negotiations began with a vision to increase cooperation and information-sharing between the U.S. and Chinese Governments on the safety of exported food and feed, and, at the request of the Chinese, to enhance the technical capacity of China's regulatory agencies to help ensure Chinese exports to the United States meet U.S. safety standards.

Secretary Leavitt also signed a Memorandum of Agreement to enhance the safety of Chinese drugs and medical devices exported to the United States.

Food and Feed Agreement>>

U.S. Department of Health & Human Services

# New Agreement Will Enhance the Safety of Drugs and Medical Devices Imported From the People's Republic of China

FOR IMMEDIATE RELEASE
Tuesday, Dec. 11, 2007

Contact: HHS Press Office
(202) 690-6343

On Dec. 11, 2007, the U.S. Department of Health and Human Services (HHS) and the State Food and Drug Administration (SFDA) of the People's Republic of China signed a Memorandum of Agreement (MOA) to enhance the safety of drugs, excipients and medical devices exported to the U.S. from China. The agreement was signed in Beijing by HHS Secretary Mike Leavitt and SFDA Commissioner Shao Mingli in advance of the third session under the United States-China Strategic Economic Dialogue.

Specifically, the two countries are establishing a bilateral mechanism to help ensure these imported products meet standards for safety and effectiveness by building quality into the process from the start. SFDA will require firms that manufacture certain products intended for export to the United States to register with SFDA. SFDA will also work toward a system that will enable it to certify that firms that manufacture products, and the products themselves, meet HHS/Food and Drug Administration (FDA) requirements.

The agreement covers the following drugs and medical devices that are manufactured in China for export to the United States: gentamicin sulfate (an antibiotic), atorvastatin (a cholesterol-lowering drug), sildenafil (a drug for erectile dysfunction), dietary supplements intended for erectile dysfunction, human growth hormone, oseltamivir (an antiviral product), cephalosporins (a class of antibiotics) manufactured in facilities that also manufacture non-cephalosporin drugs, glycerin, glucose test strips, and condoms.

**Key Terms of the Agreement**

***New Registration and Certification Requirements.*** All Chinese producers of these drugs and devices are required to register with the Chinese government, and the two countries will work together to develop and implement a program to certify that those items exported to the United States meet HHS/FDA safety standards.

To support these registration and certification programs, the two countries will conduct joint training programs and activities to cover topics such as inspection methods, clinical trials to ensure safety and the development of technical guidance documents, laws and regulations.

***Greater Information-Sharing.*** HHS/FDA and SFDA will exchange information on drugs and devices to better ensure product safety. For example, SFDA will notify HHS/FDA within 24 hours of any determination that a product sent to the United States could cause serious adverse health consequences, and also provide the tracking information necessary to identify the shipment and supplier. In the past, there was no formal system of notification between regulators in the two countries.

Within the first 30 days, HHS/FDA and SFDA will exchange lists of registered firms that manufacture certain drugs and medical devices in each country. SFDA will also provide to HHS/FDA a list of manufacturers that have been determined to be out of compliance with SFDA requirements, and access, upon request, to records concerning reviews, inspections, testing,

recalls, compliance or other testing and verification methods. SFDA will also share with HHS/FDA copies of all current Chinese regulations that cover drugs and medical products.

***Increased Access to Production Facilities.*** SFDA will assist and facilitate HHS/FDA access to relevant manufacturing sites in China.

***Stronger Product Integrity and Security.*** To guard against counterfeiting, HHS/FDA and SFDA will collaborate to establish a comprehensive electronic tracking system that applies to certain drugs at risk for counterfeiting, and enhance enforcement against producers that fail to provide tracking information. Both sides will report counterfeit drugs they identify to the World Health Organization (WHO). The two sides will develop a separate program to inform and educate supply-chain stakeholders and the public on how to avoid misbranded, adulterated or counterfeit drugs and medical devices, and how to report any they do encounter.

***Implementation and Establishing Key Benchmarks.*** SFDA and HHS/FDA will create a Working Group, which will meet within 120 days to develop a plan, to be posted online, for implementing the agreement and setting performance measures to evaluate progress. To do so, HHS/FDA will look to rely on benchmarks such as the rate at which it refuses entry of covered products to the United States; and the volume, frequency and public-health significance of products recalled, including counterfeit goods, as compared to the previous year. Senior health officials from the two countries will meet annually to discuss and review progress on the Agreement.

***Encouraging China's Involvement in International Regulatory and Public-Health Bodies.*** With support from HHS/FDA, SFDA will implement regulations and practices consistent with those established by the WHO. It will report counterfeit drugs to the WHO Secretariat and will actively participate in the organization's anti-counterfeiting task force and forum on international pharmaceutical crime. HHS/FDA will also help SFDA better understand the importance of actively reporting to the National Competent Authority Reporting program any serious adverse events that involve medical devices. This program operates through the Global Harmonization Task Force, which works to eliminate differences in the international regulation of medical devices.

**Background**

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The MOA complements the vision and goals outlined in the Action Plan, and will serve to build on efforts already underway by the U.S. Government to enhance the safety of imported products.

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Over the course of four sets of talks from July to November 2007, senior officials from HHS/FDA engaged in negotiations with senior officials from a number of agencies in the Chinese Government. The negotiations began with a vision to increase cooperation and information-sharing between the United States and Chinese Governments on the safety of exported drugs and medical devices, and, at the request of the Chinese, to enhance the technical capacity of China's regulatory agencies to help ensure Chinese exports to the United States meet U.S. safety standards.

Secretary Leavitt also signed a Memorandum of Agreement with the Chinese General Administration for Quality Supervision, Inspection and Quarantine to enhance the safety of food and feed exported from China to the United States.

Drugs and Medical Devices Agreement>>